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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,263	04/10/2006	Motoyuki Kataoka	KATAOKA3	8893

1444 7590 11/26/2008

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EXAMINER	
STOICA, ELLY GERALD	
ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
11/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,263	KATAOKA ET AL.	
	Examiner	Art Unit	
	ELLY-GERALD STOICA	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,11,16-18,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,11,16-18,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/19/2008 has been entered.

Status of the claims

2. In the amendment filed together with the request for continued examination under 37 CFR 1.114 on 09/19/2008, Applicants have cancelled claims 12-15 and 19 and amended claims 10, 11, 16-18 and 20. Claims 10, 11, 16-18, 20 and 21 are pending and are currently examined.

Withdrawn claim rejections

3. The amendments to the claims 10, 11, 16-18 and 20 as well as the cancellation of claims 12-15 and 19 and is the reason for withdrawal of all the outstanding rejections of the claims. Thus, the rejection of claims 10, 20 and 21 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn. The rejection of claims 10, 18 and 19 under 35 U.S.C. 102(b) as being anticipated by Pierce et al. (U.S. Pat. 6,689,351) is withdrawn.

Maintained clam rejections

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10, 11, 16-18, 20 and 21 remain rejected under 35 U.S.C. 102(b) as being anticipated by Shishido et al. (Nichijinshi, 33, 973-981, 1991) for the reasons of record.

To summarize, Shishido et al treated end-stage renal failure patients with human recombinant G-CSF and found it an effective and safe therapeutic agent for neutropenia and neutrophil dysfunction in patients with renal failure (Abstract). Clearly Shishido et al. teach a method of treatment of renal failure (a renal disease or nephropathy). Moreover, it is considered that end-stage renal failure is accompanied by necrosis, and thus the method of treatment of Shishido et al. inherently addresses the limitations of claims 18, 20 and 21 also. Therefore, all the consequences of the G-CSF treatment were necessarily achieved and thus the claims are anticipated by Shishido et al. The position of the Office is that the therapeutic agent's properties are inherent to its function and the activity of the agent does not stop because the use was not an intended use.

On pages 5 and 6 of the Remarks, Applicant argues that Shishido et al. does not disclose that G-CSF is effective for proliferating/or regenerating renal tissue in a diseased state of nephropathy and that the nephropathy and renal failure are different diseases, so that Shishido et al. is irrelevant to the invention.

The arguments were carefully considered but not found persuasive because, while not contending the scope of the claim 10, the broadest reasonable interpretation of the claim reads on treatment of renal tissue that is diseased. Even in the instant Application, [0009] states that one of causes of the renal failure is diabetic nephropathy. The diseased renal tissue is treated by the method of Shishido et al. as presented in the abstract and the authors gave even dosage indications (last sentence of the abstract) while clearly stating that the initial dose is for treatment of patients with renal failure. The fact is that Shishido treats the same patient as in the instant claims with the same active agent. Intention is not relevant.

Claims 10, 11, 16-18, 20 and 21 remain rejected under 35 U.S.C. 102(e) as being anticipated by Fukuda et al.

As presented previously, Fukuda et al. teaches treating renal disease by administering G-CSF to patients for whom this remedy is indicated.

On page 8 of the Remarks Applicant argues that Fukuda does not disclose repairing/regenerating renal tissue or that the administration has to be a combined Hepatocyte Growth Factor- G-CSF treatment. The arguments were carefully considered but not found persuasive because as shown above, Fukuda does teach treatment of

renal diseases with G-CSF. As stated supra, the position of the Office is that the therapeutic agent's properties are inherent to its function and the activity of the agent does not stop because the use was not an intended use. That is especially true when no dosage is claimed and there is no indication from the Specification that dosages presented by Fukuda would be ineffective for the regeneration/reparation of renal tissue. Regarding the combined administration, Fukuda et al. clearly states that G-CSF and HGF can be prepared and administered as a single preparation or alternatively, they can be prepared separately, and administered on different occasions ([0057]). Further, there are no limitations in the claims to exclude combined administration. Moreover, one of the embodiments of the instant Application clearly is culturing and regenerating cells from the renal tissue in vitro. As such other growth factors would be present in order to have a viable tissue culture in vitro.

Thus the teachings of Fukuda anticipate the claims 10--21 of the instant Application.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Conclusion

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLY-GERALD STOICA whose telephone number is (571)272-9941. The examiner can normally be reached on 8:30-17:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorraine Spector/
Primary Examiner, Art Unit 1647